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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/673,411	10/16/00	FESTO	N B-3992PCT618

EXAMINER	
ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.	Applicant(s)
09/673,411	Festo
Examiner	**Art Unit**
TAYLOR VICTOR OH	1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Mar 2, 2001*

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1, 3, 4, 6, 7, and 9-17* is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1, 3, 4, 6, 7, and 9-17* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

Claim Rejections - 35 USC § 112

1. Claims 7 , 13, and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

2. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" or "preferably " and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

In the present instance, claims 7 and 16 recite the broad recitation of " the active ingredients"and the claims also recite "-- preferably having anabolic, analgesic --"which is the narrower statement of the range/limitation.

In the present instance, claim 13 recites the broad recitation of " -- a range of more than 18 and less than 46 --"and the claim also recites "-- preferably within a range of more than 24 and less than 36--"which is the narrower statement of the range/limitation. Also, claim 13 recites the broad recitation of " -- molecular weights between about 600 and 8,000 --"and the claim also recites "-- preferably between molecular weights between about 1,000 and 4,000--"which is the narrower statement of the range/limitation. Appropriate correction is required. The Examiner recommends that the narrower statement of the range/limitation should be written in dependant claims rather than independent claims.

3. In claim 13, " -- n and m is --" is written. The claim is generally narrative and indefinite, failing to conform with current U.S. practice. It appears to be a literal translation into English from a foreign document and is replete with a grammatical and idiomatic error. Appropriate correction is required.

Claim Rejections - 35 USC § 102

2113 Product-by-Process Claims

PRODUCT-BY-PROCESS CLAIMS ARE NOT LIMITED TO THE MANIPULATION OF THE RECITED STEPS, ONLY THE STRUCTURE IMPLIED BY THE STEPS

"Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 77 F.2d 695,698,227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive prereacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated clearly by Barz et al (EP 0390206).

Barz et al disclose perfluoropolyethers with various molecular weights such as 870, 1320, and 6600 (see page 7 , lines 15-30). The compounds are identical to the claims.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1, 3-4, 6-7, 9, and 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barz et al (EP 0390206) in view of Gross et al (U.S. 5,686,102).

Barz et al teach stable emulsions containing perfluoropolyether from 0.01 to 99.9% by weight based on the total weight (see page 6 , lines 14-30) with various molecular weights such as 870, 1320, and 6600 (see page 7 , lines 24-25). Also, the applications for the emulsions are creams or pastes to prevent contact irritations and dermatitis or to protect the skin from sun (see page 6 , lines 51-54).

However, Barz et al differ from the instant invention in that perfluoropolyether is used in combination with phosphatidycholine between 0.1 % and 20 % by weight and anti-inflammatory drugs such as ibuprofen, piroxicam, and the transabsorption of drugs is increased to more than five times its normal value.

Furthermore, Gross et al teach a pharmacological composition for topical administration involved in the use of perfluoropolyethers (see col. 3 , line 19), phosphatidycholine in the range of from 30 to 99% (see col. 2 , lines 40-41) , and anti-inflammatory drugs such as ibuprofen, piroxicam (see col. 4 , lines 5-11). In addition, Gross et al have indicated that topical administration is formulated in such a way that pharmacological active compounds are delivered into a deep layer of the skin by means of a transdermal transport (see col. 1 , lines 5-11).

Concerning phosphatidycholine between 0.1 % and 20 % by weight,
Gross et al do teach that phosphatidycholine is employed in the range of from 30 to 99% (see col. 2 , lines 40-41). The claimed range and the prior art do not overlap, but they are close enough so that one skilled in the art would have obtained the claimed range by routine experimentations of the water concentration in the cleavage product.

With respect to the transabsorption of drugs increased to more than five times its normal value, the references are silent. However, Gross et al do teach that topical administration is formulated in such a way that pharmacological active compounds are delivered into a deep layer of the skin by means of a transdermal transport (see col. 1 , lines 5-11). Therefore, if the person having an ordinary skill in art had desired to improve the transdermal transport, it would have

been obvious for the skillful artisan in the art to have obtained more than five times its normal value of by routine experimentations on the formulation of the pharmacological composition for topical administration.

Therefore, if the person having an ordinary skill in art had desired to improve the formulation of the pharmacological composition for topical administration as well as to enhance the absorption of active ingredients of pharmaceutical compositions, it would have been obvious for the skillful artisan in the art to have employed Barz et al's emulsions containing perfluoropolyethers in the Gross et al's pharmacological composition for topical administration with an expectation of a similar success as in Gross et al's formulation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. Victor Oh whose telephone number is (703) 305-0809. The examiner can normally be reached on Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Geist, can be reached on (703) 308-1701. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

5/14/01

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